DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 26, 2014

I.T.S. GmbH
% Mr. Al Lippincott
Engineering Consulting Services, Inc.
3150 East 200th Street
Prior Lake, Minnesota 55372

Re: K142418
Trade/Device Name: I.T.S. Hand Locking Plates System- HLS
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulatory Class: Class II
Product Code: HRS, KTT, HWC
Dated: August 20, 2014
Received: August 28, 2014

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) NUMBER: K142418

DEVICE NAME: **I.T.S. Hand Locking Plates System - HLS**

The ***intended use*** of the *I.T.S. Hand Locking Plates System – HLS* is to draw two or more aligned bone fragments together to facilitate healing in an adult patient .

The *I.T.S. Hand Locking Plates System – HLS* **is indicated for use** in fracture fixation of:

- the phalanges,
- the metacarpal bones,
- the carpal bones,
- for arthrodesis,
- for corrective osteotomies, and
- for subcapital radial head fractures.

The I.T.S. Hand Locking Plates System is not for spinal use.

Prescription Use **XXXX** AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

NAME OF FIRM:
I.T.S. GmbH
Autal 28
Lassnitzhöehe A – 8301
AUSTRIA
www.its-implant.com

510(k) FIRM CONTACT:
Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372
Tel. No. 952-492-5858
e-mail: allippincott@msn.com

DATE: August 20, 2014

TRADE NAME: **I.T.S. Hand Locking Plates System - HLS**

COMMON NAME: Small Bone Plating System, Compression Screw

CLASSIFICATION: Plate, Fixation, Bone & Screw, Fixation, Bone

Smooth or threaded metallic bone fixation appliances and accessories (per 21 CRF, Sec. 888.3040).

Single/Multiple Component Metallic Bone Fixation Appliances and Accessories (per 21 CRF, Sec. 888.3030).

DEVICE PRODUCT CODE: **HRS**

SUBSEQUENT PRODUCT CODE: **KTT, HWC**

SUBSTANTIALLY EQUIVALENT DEVICES
Stryker – Hand Plating System (**K961497 & K060613**)
Synthes – LCP Compact Hand 1.5 (**K092247**)
Biomet/DePuy - ALPS Small Bone Locked Plating System (**K101240, K061748 & K041081**)
I.T.S. GmbH – Extremity Fixation Systems (**K131722**)

DEVICE DESCRIPTION: The *I.T.S. Hand Locking Plates System – HLS* consists of Predicate small bone trauma implant components commonly found with large companies with orthopedic markets in the United States. The I.T.S. HLS System consists of 1.0 and 1.5mm thick plates in Straight, T-Shape, Y-Shape, L-Shape (Left & Right), Extended and Square Plate configurations (with multiple hole sizing) that utilize both Locking and Non-Locking self-tapping Screws in 1.5mm, 1.8mm and 2.3mm sizes in various lengths. A 2.0mm Headless Compression Screw in various lengths is also available.

DEVICE DESCRIPTION Continued:

All small plate components are manufactured from Commercialy Pure (CP) Titanium material to ASTM F67 and allow for minor intra-operative forming/contouring by the surgeon to fit the small bone anatomy. All screws consist of a 6-4 Alloyed Titanium material to ASTM F136. All I.T.S. small plates and screws are processed with an anodize DOTIZE surface treatment. The low-profile and contoured small plate design minimizes soft-tissue irritation for the patient.
Associated instrumentation such as Plate Holder, Drills, Drill Guides, Depth Guage, Countersink Reamers, Guide Wire and ancillary instrumentation is available. All small plates and screws are provided **Non-Sterile**.

INTENDED USE:

The ***intended use*** of the *I.T.S. Hand Locking Plates System – HLS* is to draw two or more aligned bone fragments together to facilitate healing in an adult patient.

The *I.T.S. Hand Locking Plates System – HLS* **is indicated for use** in fracture fixation of:

- the phalanges,
- the metacarpal bones,
- the carpal bones,
- for arthrodesis,
- for corrective osteotomies, and
- for subcapital radial head fractures.

The I.T.S. Hand Locking Plates System is not for spinal use.

EQUIVALENCE:

The I.T.S. GmbH Hand Locking Plates System - HLS is Substantially Equivalent (SE) to the Stryker, Synthes, Biomet/DePuy and I.T.S. GmbH bone plate/screw systems. No nonclinical testing was used in the determination of Substantial Equivalence (SE).

SUMMARY OF TECH-NOLOGICAL CHAR-ACTERISTICS

The I.T.S. GmbH Hand Locking Plates System – HLS is Similar in Material, Geometry Design/Markings, and Indications to Stryker, Synthes and Biomet/DePuy predicate system(s) currently sold in the U.S. market.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The I.T.S. GmbH Hand Locking Plates System - HLS is shown to be safe and effective for use in fracture fixation of small bones in the hand.